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Attorneys for Defendant United Therapeutics Corporation

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SANDOZ INC. AND RAREGEN,
LLC,

Plaintiffs,

v.

UNITED THERAPEUTICS
CORPORATION AND SMITHS
MEDICAL ASD, INC.,

Defendants.

Civil Action No. 3:19-cv-10170-BRM-
LHG

**DEFENDANT UNITED THERAPEUTICS CORPORATION'S ANSWER
AND AFFIRMATIVE DEFENSES TO PLAINTIFFS SANDOZ INC. AND
RAREGEN LLC'S COMPLAINT**

Defendant United Therapeutics Corporation ("UTC"), by counsel, hereby
files its Answer to Plaintiffs Sandoz Inc. ("Sandoz") and RareGen, LLC's

(“RareGen,” and together with Sandoz, “Plaintiffs”) Complaint (ECF No. 1). All responses are based solely on the knowledge and information of UTC. Unless otherwise stated, UTC does not purport to admit or characterize the conduct of another defendant. To the extent the headings in the Complaint contain factual allegations to which a response is required, they are denied. All other allegations not specifically admitted are denied. UTC reserves the right to amend its Answer, in whole or in part.

1. The allegations in Paragraph 1 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 1.

2. UTC admits that Pulmonary Arterial Hypertension (“PAH”) is a condition characterized by high blood pressure in the pulmonary arteries and that, in many circumstances, it can be life-threatening. UTC admits that some PAH patients use infusion pumps, some of which are manufactured by Smiths Medical ASD, Inc. (“Smiths”) and some of which utilize single-use cartridges, to administer treprostinil, a PAH medication. UTC further admits that treprostinil has been used to extend the lives of PAH patients. UTC otherwise denies the allegations in Paragraph 2 of the Complaint.

3. UTC admits that Sandoz introduced generic treprostinil in March 2019. UTC is informed and believes that Sandoz was the first manufacturer of

generic treprostinil to come to market. UTC otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint and on that basis denies them.

4. UTC admits that it manufactures and markets Remodulin® (treprostinil) Injection (“Remodulin”) and that Remodulin’s active ingredient is treprostinil. UTC further admits that it entered into certain agreements with Smiths and with certain specialty pharmacies. Those agreements are the best record of their content, and UTC denies Plaintiffs’ characterization of them. UTC otherwise denies the allegations in Paragraph 4 of the Complaint.

5. The allegations in Paragraph 5 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 5.

6. The allegations in the first and last sentences of Paragraph 6 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in those sentences. UTC admits that, in 2016, 2017, and 2018, it generated net sales of approximately \$602.3 million, \$670.9 million, and \$599 million on Remodulin, respectively. UTC further admits that such sales accounted for more than 35% of its total revenues for those years. UTC otherwise denies the allegations in Paragraph 6.

7. The allegations in Paragraph 7 of the Complaint consist of Plaintiffs' characterization of their purported claims, to which no answer is required. To the extent an answer is required, UTC denies the allegations and denies that Plaintiffs are entitled to any relief.

8. UTC lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8 of the Complaint and on that basis denies them.

9. UTC admits on information and belief that RareGen is a limited liability company organized under Delaware law. UTC lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 9 of the Complaint and on that basis denies them.

10. UTC admits that it researches, develops, markets, and sells therapies designed to treat patients with PAH, including Remodulin® (treprostinil) Injection, Tyvaso® (treprostinil) Inhalation Solution, Orenitram® (treprostinil) Extended-Release Tablets, and Adcirca® (tadalafil). UTC further admits that it is incorporated under Delaware law. UTC admits that it has executive offices located at 1040 Spring Street, Silver Spring, Maryland. UTC otherwise denies the allegations in Paragraph 10 of the Complaint.

11. UTC lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11 of the Complaint and on that basis denies them.

12. The allegations in Paragraph 12 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC admits that Plaintiffs' Complaint purports to allege violations of 15 U.S.C. §§ 1, 2, 15, and 26, and otherwise denies the allegations in Paragraph 12.

13. The allegations in Paragraph 13 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC admits that this Court has original jurisdiction over federal antitrust claims pursuant to 28 U.S.C. § 1337, and otherwise denies the allegations of Paragraph 13.

14. The allegations in Paragraph 14 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 14.

15. The allegations in Paragraph 15 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 15.

16. The allegations in Paragraph 16 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 16.

17. UTC admits that patients with PAH often experience symptoms such as shortness of breath, fatigue, weakness, chest pain, light-headedness, and fainting. UTC refers to the New York Heart Association's guidelines for their content and denies any characterization of them. UTC otherwise denies the allegations in Paragraph 17 of the Complaint.

18. UTC denies the first sentence of Paragraph 18 of the Complaint. The remainder of Paragraph 18 quotes selectively from a statement made by UTC's CEO. As a purported summary of a longer and more complete statement, this selective quotation is necessarily incomplete, and on that basis UTC denies the allegations in the remainder of Paragraph 18.

19. UTC admits that Remodulin is a parenteral therapy that is administered either subcutaneously or intravenously. UTC further admits that, in its 2018 10-K, it stated: "Patients who receive therapy through implanted venous catheters have a risk of developing blood stream infections and a serious systemic infection known as sepsis. As a result, subcutaneous administration is the preferred method of Remodulin delivery for the majority of patients, representing a

majority of the U.S. Remodulin patients.” UTC otherwise denies the allegations in Paragraph 19 of the Complaint.

20. UTC admits that the CADD-MS® 3 (“CADD-MS 3”) pump was manufactured by Smiths and that it can be used to administer subcutaneous injections of Remodulin. To the extent that cell phones vary in size, UTC denies the allegations in the second sentence of Paragraph 20 of the Complaint. UTC denies the allegations in the third sentence of Paragraph 20 insofar as they suggest that CADD-MS 3 pumps remain in consistent operation, and otherwise admits the allegations in the third sentence. UTC further admits the allegations in the final sentence of Paragraph 20. UTC otherwise denies the allegations in Paragraph 20.

21. Denied.

22. UTC admits that PAH patients who have been prescribed Remodulin may receive their Remodulin from either Accredo Health Group, Inc. or CVS Specialty Pharmacy and otherwise denies the allegations in the first sentence of Paragraph 22 of the Complaint. UTC admits the allegations in the final sentence of Paragraph 22.

23. Admitted.

24. On information and belief, UTC admits that prior to March 25, 2019, no generic versions of injected treprostinil were being lawfully sold in the United States.

25. Denied.

26. Admitted.

27. UTC refers to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (“FDCA”), for its content and denies any characterization of it. UTC otherwise denies the allegations in Paragraph 27 of the Complaint.

28. The allegations in Paragraph 28 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC refers to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 (“Hatch-Waxman Act”), for its content and denies any characterization of it or its purpose.

29. UTC admits that generic medications frequently contain the same active ingredient as their corresponding reference listed drugs. UTC lacks sufficient information to respond to the allegations in the third sentence of Paragraph 29 of the Complaint because no source material is provided, and on that basis denies them. UTC otherwise denies the allegations in Paragraph 29.

30. Denied.

31. The allegations in Paragraph 31 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC refers to the FDCA and the Hatch-Waxman Act for their content and denies any characterization of them.

32. The allegations in Paragraph 32 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC refers to the Hatch-Waxman Act for its content and denies any characterization of it. UTC admits that the FDA generates a list of patents associated with FDA-approved medications in a publication known as the “Orange Book.”

33. The allegations in Paragraph 33 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC refers to the Hatch-Waxman Act for its content and denies any characterization of it or its purposes.

34. The first sentence of Paragraph 34 is admitted. The second sentence of Paragraph 34 is admitted on information and belief.

35. Admitted.

36. UTC admits that it sued Sandoz for patent infringement related to the patents covering Remodulin. UTC otherwise denies the allegations in Paragraph 36 of the Complaint.

37. Admitted.

38. On information and belief, admitted.

39. UTC denies the allegations in the first sentence of Paragraph 39 of the Complaint. Regarding the second, third, and fourth sentences of Paragraph 39,

UTC admits that it develops new and innovative therapies for its patients, and that Plaintiffs have selectively quoted from statements made by its CEO. As a purported summary of these statements, the quoted portions are necessarily incomplete, and on that basis UTC denies the allegations in the second, third, and fourth sentences of Paragraph 39 and denies any characterization of the quoted material. UTC admits that, during a May 5, 2016 health care conference, its CEO stated:

Remodulin is going to lose patent coverage in the 2017-2018 timeframe. And we have signed a settlement agreement with Sandoz for the launch of a generic form of Remodulin in mid-2018. So, I think that there is definitely a risk of generic Remodulin erosion in the second half of 2018. Now we have taken a couple of steps to ameliorate that.

One of our kind of mantras around our company in terms of dealing with generic is to make generic barbaric. And what that means is to advance the therapy so much that if you were using the generic drug that is not how you would want a member of your family treated for pulmonary hypertension. It would be so old-school that it would seem, quote/unquote, barbaric.

UTC also admits that, during an August 15, 2017 health care conference, its CEO stated:

The concept of generic drugs is a good concept because it forces the branded or the ethical pharmaceutical companies to keep advancing the state of the art in medicine to have a good business. And we created a mantra that we use around United Therapeutics called make generic barbaric. And that little mantra reminds us that our job is to advance the state of patient care so rapidly that generic technologies and generic drug delivered to old devices will seem barbaric.

UTC otherwise denies the allegations in Paragraph 39.

40. UTC admits that, in the interests of PAH patients, it is working in collaboration with Medtronic plc (“Medtronic”) to develop an implantable pump delivery system for Remodulin formerly referred to as RemoSynchron™, and now referred to as the Implantable System for Remodulin® (“ISR”) and that the system is a fully implantable pump used to deliver Remodulin through intravenous injections, and, on information and belief, may serve as an alternative method to existing intravenous delivery systems. UTC further admits that the ISR, like many of the innovative therapeutic solutions UTC helps develop, is designed to promote patient comfort, convenience, and safety. Finally, regarding the statements quoted in Paragraph 40 of the Complaint, UTC admits that Plaintiffs have quoted selectively from statements made by its CEO; as a purported summary and characterization of those comments, those allegations of Paragraph 40 are necessarily incomplete, and on that basis UTC denies them. UTC otherwise denies the allegations in Paragraph 40 of the Complaint.

41. UTC admits that it initially planned to launch the ISR in 2017, and that regulatory hurdles have since delayed that launch. UTC further admits that it announced the ISR’s launch delay on April 3, 2017. Finally, on information and belief, UTC admits that the FDA conditionally cleared Medtronic’s Premarket Approval Application for the ISR in July 2018, but that it cannot be launched until

Medtronic satisfies certain conditions outlined in the FDA's clearance. UTC otherwise denies the allegations in Paragraph 41 of the Complaint.

42. UTC admits that, in the interests of PAH patients, it is working in collaboration with DEKA Research and Development Corporation ("DEKA") to develop a new subcutaneous infusion pump known as the RemUnity® ("RemUnity") pump for the administration of Remodulin to replace or supplement the discontinued CADD-MS 3 platform. UTC lacks sufficient information to respond to the allegations in the final sentence of Paragraph 42 of the Complaint because no source is provided, and on that basis denies them. UTC otherwise denies the allegations in Paragraph 42.

43. UTC admits that DEKA applied for FDA clearance of the RemUnity pump in February 2018 and otherwise denies the allegations in Paragraph 43 of the Complaint.

44. UTC admits that it has developed or is developing new and innovative therapies for its patients, including the RemoLife® ("RemoLife") infusion system in conjunction with Smiths and the Trevyent® ("Trevyent") pump. UTC further admits that it acquired the Trevyent pump through its acquisition of SteadyMed Ltd. in August 2018. Finally, UTC admits that it is developing the RemoLife and Trevyent pumps for use with treprostinil solution. UTC otherwise denies the allegations in Paragraph 44 of the Complaint.

45. UTC lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 45 of the Complaint and on that basis denies them.

46. UTC lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 46 of the Complaint and on that basis denies them. UTC admits that, as of late 2018, it had not yet launched the RemUnity, RemoSynch, RemoLife, or Trevyent pumps. UTC otherwise denies the allegations in Paragraph 46.

47. UTC lacks direct knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 47 of the Complaint and on that basis denies them.

48. To the extent the allegations in Paragraph 48 of the Complaint pertain to UTC, UTC denies them. To the extent the allegations in Paragraph 48 pertain to another defendant, UTC lacks knowledge or information sufficient to form a belief as to the truth of the allegations and on that basis denies them.

49. The allegations in Paragraph 49 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC admits that it entered into a Third Amendment to its supply agreement with Smiths, refers to that document for its contents, and denies any characterization of it. UTC otherwise denies the allegations in Paragraph 49.

50. UTC admits that it contracted with Smiths to purchase cartridges to serve UTC's Remodulin patients, and otherwise denies the allegations in Paragraph 50 of the Complaint.

51. UTC admits that the language quoted in Paragraph 51 of the Complaint appeared in UTC's 2018 10-K, but denies any characterization of it. UTC otherwise denies the allegations in Paragraph 51.

52. Denied.

53. UTC admits that among the FDA-approved classes of therapies designed to treat PAH are the endothelin receptor antagonists ("ERAs"); phosphodiesterase type-5 inhibitors ("PDE-5s"); and prostacyclins. UTC denies any implication that these are the sole therapeutic classes used to treat PAH, and otherwise denies the allegations in Paragraph 53 of the Complaint.

54. Admitted.

55. UTC admits that a PAH patient's treatment program is based, at least in part, on the treating physician's judgment, which may at times take into account the severity of the patient's symptoms. UTC otherwise denies the allegations in Paragraph 55 of the Complaint.

56. The first sentence in Paragraph 56 of the Complaint sets forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in the first sentence of Paragraph 56. UTC admits that

Plaintiffs have selectively quoted from statements UTC's CEO made during a May 5, 2016 health care conference, but denies Plaintiffs' characterization of the statement and denies that the quote accurately reflects the context in which the statement was made. UTC otherwise denies the allegations in Paragraph 56 of the Complaint.

57. The allegations in Paragraph 57 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 57.

58. UTC admits that there are two categories of FDA-approved parenteral prostacyclin therapies on the market today: those with the active ingredient epoprostenol and those with the active ingredient treprostinil. UTC further admits there are differences between those two categories. UTC otherwise denies the allegations in Paragraph 58 of the Complaint.

59. UTC admits that Plaintiffs have selectively quoted from UTC's 2018 10-K, but denies any characterization of it. As a purported summary of UTC's statements, the allegations in Paragraph 59 of the Complaint are necessarily incomplete, and on that basis UTC denies them.

60. UTC admits that treprostinil is the only PAH therapy approved by the FDA that can be administered through subcutaneous injections in the United States today. UTC otherwise denies the allegations in Paragraph 60 of the Complaint.

61. UTC lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 61 of the Complaint and on that basis denies them. UTC admits that a physician must prescribe Remodulin injections before a patient can receive the treatment and that UTC's PAH patients receiving physician-prescribed subcutaneous Remodulin injections typically administer their medication using the CADD-MS 3 platform. UTC lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in the second sentence of Paragraph 61 and on that basis denies them. UTC otherwise denies the allegations in Paragraph 61.

62. The allegations in Paragraph 62 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 62.

63. Admitted.

64. The allegations in Paragraph 64 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 64.

65. UTC admits that Plaintiffs have selectively quoted from statements made by its CEO in Paragraph 65 of the Complaint, but denies any characterization of them and denies that the Complaint accurately reflects the context in which the statement was made.

66. UTC admits that the allegations in the first sentence of Paragraph 66 of the Complaint describe one possible treatment option for PAH patients exhibiting less severe symptoms, but otherwise denies the allegations in the first sentence of Paragraph 66. UTC admits that Plaintiffs have selectively quoted from statements made by its CEO in Paragraph 66, but denies any characterization of them and denies that the statement is an accurate characterization of current PAH treatment practices.

67. UTC admits that Plaintiffs have selectively quoted from statements made by its CEO in Paragraph 67 of the Complaint, but denies any characterization of them.

68. Denied.

69. The allegations in Paragraph 69 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 69.

70. The allegations in Paragraph 70 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 70.

71. UTC admits that it was the sole provider of subcutaneous treprostinil in the United States prior to generic entry. UTC otherwise denies the allegations in Paragraph 71 of the Complaint.

72. UTC denies the allegations in the first sentence of Paragraph 72 of the Complaint. UTC admits that Plaintiffs have selectively quoted statements made by UTC in the second and third sentences of Paragraph 72, but denies any characterization of them. The final sentence of Paragraph 72 appears to be quoting from a document authored by the World Health Organization (“WHO”). To the extent the allegation quotes said document, UTC refers to that document for its contents and denies any characterization of them. UTC otherwise denies the allegations in Paragraph 72.

73. UTC denies the allegations in the first sentence of Paragraph 73 of the Complaint. The allegations in the fourth sentence of Paragraph 73 are vague, and on that basis UTC denies them. UTC admits that, in order for a prescription medication to be lawfully marketed, sold, and prescribed to patients in the United States, it must first receive FDA approval. UTC further admits that there are five FDA-approved injected prostacyclins used to treat PAH available in the United States today: Remodulin, generic treprostinil, Flolan, Veletri, and generic epoprostenol. UTC otherwise denies the allegations in Paragraph 73.

74. UTC admits that the FDA has granted approval to at least one form of generic treprostinil. UTC otherwise denies the allegations in Paragraph 74 of the Complaint.

75. UTC lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 75 of the Complaint and on that basis denies them. UTC admits that its PAH patients receiving physician-prescribed subcutaneous Remodulin injections typically administer their medication using the CADD-MS 3 platform, but otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of Paragraph 75, and on that basis denies them. UTC otherwise denies the allegations in Paragraph 75.

76. The allegations in the first sentence of Paragraph 76 of the Complaint are vague, and UTC lacks knowledge or information sufficient to form a belief as to their truth and, on those bases, UTC denies them. The last sentence of Paragraph 76 sets forth legal conclusions to which no response is required. To the extent a response is required, UTC denies the remaining allegations in Paragraph 76.

77. Denied.

Count 1: Restraint of Trade (15 U.S.C. § 1)

78. UTC hereby incorporates each preceding and succeeding paragraph as though fully stated herein.

79. UTC admits that it entered into a contract with Smiths whereby Smiths would manufacture certain CADD-MS 3 pumps and cartridges for UTC's

Remodulin patients but otherwise denies the allegations in Paragraph 79 of the Complaint regarding the substance of alleged contracts between Defendants. The remaining allegations in Paragraph 79 set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the remaining allegations in Paragraph 79.

80. The allegations in Paragraph 80 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 80.

81. The allegations in Paragraph 81 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 81.

82. The allegations in Paragraph 82 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 82.

Count 2: Monopolization (15 U.S.C. § 2)

83. UTC hereby incorporates each preceding and succeeding paragraph as though fully stated herein.

84. UTC admits that it entered into a contract with Smiths whereby Smiths would manufacture certain CADD-MS 3 pumps and cartridges for UTC's Remodulin patients but otherwise denies the allegations in Paragraph 84 regarding

the substance of alleged contracts between Defendants. The remaining allegations in Paragraph 84 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the remaining allegations in Paragraph 84.

85. The allegations in Paragraph 85 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 85.

86. The allegations in Paragraph 86 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 86.

87. The allegations in Paragraph 87 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 87.

Count 3: Restraint of Trade (N.J. Stat. Ann. § 56:9–3)

88. UTC hereby incorporates each preceding and succeeding paragraph as though fully stated herein.

89. UTC admits that it entered into a contract with Smiths whereby Smiths would manufacture certain CADD-MS 3 pumps and cartridges for UTC's Remodulin patients but otherwise denies the allegations in Paragraph 89 of the Complaint regarding the substance of alleged contracts between Defendants. The

remaining allegations in Paragraph 89 set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the remaining allegations in Paragraph 89.

90. The allegations in Paragraph 90 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 90.

91. The allegations in Paragraph 91 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 91.

Count 4: Restraint of Trade (N.C. Gen. Stat. § 75–1)

92. UTC hereby incorporates each preceding and succeeding paragraph as though fully stated herein.

93. UTC admits that it entered into a contract with Smiths whereby Smiths would manufacture certain CADD-MS 3 pumps and cartridges for UTC's Remodulin patients but otherwise denies the allegations in Paragraph 93 of the Complaint regarding the substance of alleged contracts between Defendants. The remaining allegations in Paragraph 93 set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the remaining allegations in Paragraph 93.

94. The allegations in Paragraph 94 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 94.

95. The allegations in Paragraph 95 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 95.

Count 5: Unfair Trade Practices (N.C. Gen. Stat. § 75–1.1)

96. UTC hereby incorporates each preceding and succeeding paragraph as though fully stated herein.

97. The allegations in Paragraph 97 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 97.

98. The allegations in Paragraph 98 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 98.

99. The allegations in Paragraph 99 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 99.

Count 6: Tortious Interference with Prospective Economic Advantage

100. UTC hereby incorporates each preceding and succeeding paragraph as though fully stated herein.

101. UTC lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 101 of the Complaint and on that basis denies them.

102. The allegations in Paragraph 102 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 102.

103. The allegations in Paragraph 103 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, UTC denies the allegations in Paragraph 103.

Demand for Jury Trial

104. UTC admits that Plaintiffs purport to demand a jury trial.

Prayer for Relief

105. UTC admits that Plaintiffs purport to seek the relief identified in Paragraph 105 of the Complaint. To the extent any further answer is required to Paragraph 105, the Court has denied Plaintiffs' request for a preliminary injunction (ECF No. 169), and UTC denies any remaining allegations and states that Plaintiffs

are not entitled to any relief, including without limitation the remedies set out in the Complaint.

AFFIRMATIVE DEFENSES

UTC asserts the following defenses to the Complaint. Further, UTC reserves all defenses under Federal Rule of Civil Procedure 8(c) and any other defenses, at law or in equity, that may be available based on discovery and further factual investigation in the case. UTC undertakes the burden of proof as to only those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein. UTC reserves the right to assert any and all defenses on which it does not bear the burden of proof.

First Defense

The Complaint fails, in whole or in part, to state a claim upon which relief may be granted.

Second Defense

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs failed to make reasonable efforts to mitigate damages, if any, allegedly suffered as a result of the conduct they allege.

Third Defense

Plaintiffs' claims are barred, in whole or in part, because one or both Plaintiffs lack standing to bring such claims and/or have not sustained cognizable antitrust injury attributable to UTC's conduct.

Fourth Defense

Plaintiffs' claims are barred, in whole or in part, under the doctrine of unclean hands and/or *in pari delicto*.

Fifth Defense

Plaintiffs' claims are barred, in whole or in part, because the alleged conduct is the result of the competitive process and has led to actual pro-competitive results, and the pro-competitive benefits of UTC's alleged conduct substantially outweigh any purportedly anticompetitive effects.

Sixth Defense

To the extent the Complaint could be read as seeking punitive damages, such damages are not available in this action.

Seventh Defense

To the extent the Complaint could be read as seeking damages for each of the stated Causes of Action, such damages would be duplicative.

Eighth Defense

Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitation and/or the doctrines of laches, waiver, and/or estoppel.

Ninth Defense

Plaintiffs' claims are barred, in whole or in part, because their alleged damages are not attributable to UTC's conduct, but instead are the result of Plaintiffs' own conduct.

Tenth Defense

UTC incorporates by reference any defenses applicable to it that are asserted by any other defendant to the Complaint as if set forth fully herein.

PRAYER FOR RELIEF

WHEREFORE, UTC hereby requests that Plaintiffs' Complaint be dismissed in its entirety, with prejudice; that any and all of Plaintiffs' claims for damages or other relief of any sort be denied; that UTC be awarded costs, disbursements, and reasonable attorneys' fees; and that UTC be awarded any such other and further relief as this Court may deem just and proper.

Dated: February 12, 2020

/s/ Stephen M. Orlofsky

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Attorneys for Defendant United Therapeutics Corporation

CERTIFICATE OF SERVICE

I hereby certify that, on this 12th day of February, 2020, I caused a copy of the foregoing Answer and Affirmative Defenses of be served upon all counsel of record via the Court's CM/ECF system.

Dated: February 12, 2020

/s/ Stephen M. Orlofsky
Stephen M. Orlofsky